K110451

510(k) Summary

[As Required by 21 CFR 807.92(c)]

AUG 26 2011

May 22, 2011

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Official Contact: Brandon Hansen
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Trade Name: Intuitive Surgical EndoWrist® One Suction/Irrigator

Common Name: system, surgical, computer controlled instrument

Classification: endoscope and accessories, 21 CFR 876.1500, NAY

Predicate Device: Surgiflex® WAVE™ Suction-Irrigation System (K992126)

Device Description: The EndoWrist® One Suction/Irrigator is a single-use, disposable instrument developed for use with the da Vinci Surgical System. The instrument provides the surgeon with the ability to activate suction and irrigation directly from the surgeon console. Activation will be controlled through the foot pedal at the surgeon side console. An additional feature allows manual activation by the patient side assistant. The suction and irrigation sources are supplied by conventional devices (suction - canister, hospital line, etc; and irrigation - closet, compressed air, gravity flow, etc) that are normally available in an operating room setting.

Intended Use: The EndoWrist® One Suction/Irrigator, when attached to an external suction/irrigation source(s), is intended for use with the da Vinci Si Surgical System as a general purpose suction and/or irrigation device used during surgical procedures.

Technological Characteristics: The EndoWrist® One Suction/Irrigator is equivalent to the predicate device in terms of its indications for use, design, technology and performance specifications.

Performance Data: Performance tests (bench and animal lab tests) were conducted to demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The results of the testing did not raise any new issues of safety or effectiveness as compared to the predicate device for the same indications for use.

K110457

Summary: Based on the intended use, technical characteristics and performance data, the EndoWrist® One Suction/Irrigator is equivalent to the predicate device in terms of safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Intuitive Surgical, Inc.
% Mr. Brandon Hansen
Sr. Manager, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

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Re: K110451
Trade/Device Name: EndoWrist® One Suction/Irrigator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: August 02, 2011
Received: August 08, 2011

Dear Mr. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if known: K110451

Device Name: EndoWrist® One Suction/Irrigator

INDICATION FOR USE:

The EndoWrist® One Suction/Irrigator, when attached to an external suction/irrigation source(s), is intended for use with the da Vinci Si Surgical System as a general purpose suction and/or irrigation device used during surgical procedures.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

E. J. Keith

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110451